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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,567	03/26/2001	Kumar Subramanian	Kum13Sil.Lan	9915

7590 07/14/2004

PENNIE AND EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036-2711

EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/817,567

Applicant(s)

SUBRAMANIAN ET AL.

Examiner

D. Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24-27, 31-34, 36-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-27, 31-34, 36-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Drawings***

The new drawings filed January 2, 2002 are objected to under 35 U.S.C. 132 because they introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Figs. 3A-3C.

Applicant is required to cancel the new matter.

### ***Specification***

In the specification, the amendments filed January 2, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment added after page 5, line 33, and the paragraph added after page 8, line 32. These amendments to the specification are directed to the newly filed drawings of Figs. 3A-3C, all of which are new matter.

Applicant is required to cancel the new matter.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-27, 31-34 and 36-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The limitations identified in the claims cite new subject matter. The particular claims cited are for example only and do not encompass all of the claims containing the new subject matter limitations. Therefore, applicants are required to appropriately amend all claims containing the new subject matter. Italicized phrases emphasize the portion of the limitation that constitutes new matter as needed.

Claim 24: "A continuous *cutting* profile." "Cutting" is not recited in the original disclosure, nor do the drawings support such a term.

Claim 25: The term "width" and its intended meaning is new matter. The intended meaning of the term "thickness" as described in the claims constitutes new matter since the meaning presently used in the claims is different from the specification.

Claim 31: "the penetration portion terminates *in a chisel-shaped point* at the penetration end."

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Claim 37: "the silicon substrate has a *thickness* cross-section dimension of at least about 25 micrometers."

Claim 41: "The penetration end of the silicon substrate has a *thickness cross-section* dimension of at least about 50 micrometers at the penetration end of the sharp point."

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-26, 31-34, 38, 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisano et al. (US 5,928,207). Pisano discloses a microlancet device 20 for obtaining blood samples comprising an elongated single crystal silicon substrate having a base portion 24 and a penetration portion 22 and 40. The penetration portion has a sharp point 40. The width and thickness of the penetration portion narrow to become a sharp point.

As illustrated, the cross-section of the penetration end forms a sharp point. Also, the patent states that the device extends from a near infinitesimally small point to the maximum width and thickness dimensions of the penetration portion. Hence, the penetration portion must at some point have a cross-section of about 50 micrometers in

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width and thickness, excluding the sharp point. As a result, the penetration portion extends from about 250 to about 50 micrometers in thickness and in width. The lancet is inherently disposable. The distal end has a chiseled portion, which is the beveled sides of the tip.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pisano et al. in view of Lin et al. (US 5,591,139). Pisano is silent regarding the length of the penetration portion. Nevertheless, Lin teaches a microlancet device for taking a blood sample wherein the needle is between about 1 and 6 millimeters (Col. 4, lines 11-14) to pierce the outer tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make Pisano's needle between about 1 and 6 millimeters as taught by Lin, in order to pierce the outer tissue and obtain a blood sample.

***Response to Arguments***

Applicant's arguments filed May 26, 2004 have been fully considered but they are not persuasive. Examiner concludes that the Pisano penetration portion provides a smooth continuous profile, as claimed by applicants. The right angles between the lancet shaft and penetration portion are not relevant to the profile of the penetration portion.

The affidavit filed May 3, 2004 has been considered with respect to the new matter rejections.

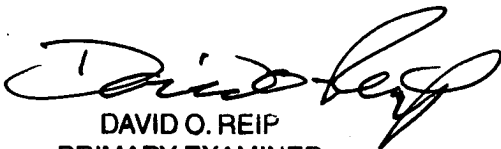
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD  
July 2, 2004

  
DAVID O. REIP  
PRIMARY EXAMINER